"ladite sequence nucléotidique étant *pourvue* de son condon d'initiation" (emphasis added) was used in the specification and in claim 1. The original translation improperly translated this phrase as, "said nucleotide sequence *lacking* its initiation codon." (Emphasis added.) However, the correct translation of the French word *pourvue* is "having," or "being provided with." Thus, these amendments are very clearly supported by the application as originally filed.

RESTRICTION

In the Office Action dated March 26, 2003, the Examiner required restriction under 35 U.S.C. § 121 between the following groups:

I. Claims 75-86, 100, 116, 117 and 118, drawn to a vector, classified in class 435, subclass 320.1 and a recombinant mycobacterium, classified in class 435, subclass 253.1.

II. Claims 87-88, drawn to a method of screening for nucleotide sequences, classified in class 435, subclass 6.

III. Claims 89-92, drawn to a library, classified in class 436, subclass 536.

IV. Claims 93-98, 101, 102, 103 and 107, drawn to a nucleotide, classified in class 536, subclass 23.1.

V. Claims 99, 104-106 and 120, drawn to a polypeptide, classified in class 530, subclass 350.

VI. Claims 108-115, drawn to primers and probes, classified in class 536, subclass 24.3.

VII. Claims 119, 120 and 124, drawn to a method of preparing a polypeptide, classified in class 435, subclass 69.1.

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VIII. Claims 12 1-122, drawn to a hybrid polypeptide, classified in class 435, subclass 69.7.

IX. Claim 123, drawn to a polynucleotide encoding a hybrid polypeptide, classified in class 536, subclass 23.1.

X. Claim 125, drawn to a method for in vivo detection of antibodies, classified in class 435, subclass 69.1.

XI. Claims 126 and 127, drawn to a method for detection of an infection and kit for same, classified in class 435, subclass 6.

XII. Claims 128 and 129, drawn to mono- or polyclonal antibodies, classified in class 424, subclass 130.1.

XIII. Claims 130 and 131, drawn to a method for the specific detection of the presence of an antigen and kit, classified in class 435, subclass 6.

XIV. Claims 132-138, drawn to a method for the detection and rapid identification of mycobacterium, classified in class 435, subclass 6.

XV. Claims 139 and 140, drawn to a kit, classified in class 435, subclass 6.

XVI. Claim 141, drawn to an immunogenic composition, classified in class 530, subclass 387.1.

XVII. Claims 142-144, drawn to a vaccine, classified in class 514, subclass 44.

XVIII. Claims 145-146, drawn to a method of screening, classified in class 435, subclass 6.

XIX. Claim 147, drawn to a molecule for inhibiting growth of a mycobacterium, classified in class 514, subclass 44.

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The Office further indicated that this application contains claims directed to patentably distinct species of the claimed invention, which requires further restriction. In particular, the Office stated that the nucleotide sequences and amino acid sequences of the instant claims are subject to a restriction requirement. Absent evidence to the contrary, the Office stated, each nucleotide or amino acid sequence is presumed to represent an independent and distinct invention subject to restriction under 35 U.S.C. § 121 and 37 C.F.R. § 1.141 *et seq*.

RESPONSE TO RESTRICTION:

Initially, in response to the restriction requirement, Applicants note that claim 1 is pending. Indeed, all of the claims identified as part of Group I depend ultimately from claim 1. As such, Applicants respectfully submit that claim 1 should be part of Group 1.

Election

Applicants provisionally elect to prosecute the claims of Group I, including claim 1, with traverse. Applicants further provisionally elect the sequence of SEQ ID NO:1, with traverse.

Traversal

In the Office Action, the Office states that inventions I, III, IV, V, VI, VII, IX, X, XIII, XVI, XVII, XVII [sic, XVIII?], and XX are patentably distinct because they are chemically, biologically, structurally, and functionally different, and are capable of separate use. (Office Action, page 4, first full paragraph, lines 1-3.) The Office states that the inventions of Group I and III-IV are biologically and functionally different and distinct (Office Action, page 4, second paragraph, lines 1-2), and that the products of Group I are not used in the methods of Groups II, VIII, XI, XII, XIV, XV, and XIX and that the

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operation, function, and effects of the products are completely different (Office Action, page 4, second paragraph, lines 2-5.) Finally, the Office alleges that the inventions of Groups II, VIII, XI, XII, XIV, XV, and XIX are distinct methods from each other, having different starting materials, different outcomes, and different uses, such that they are separately patentable. (Office Action, page 5, lines 1-4.)

Applicants respectfully submit that while the reasons provided by the Office are *factors* in determining whether claims should be examined together, they are not the *only* factors. For example, it is respectfully submitted that the subject matter of all pending claims is sufficiently related that a thorough search of the subject matter of any one group of claims would encompass a search for the subject matter of the remaining claims. Thus, a search and examination of the non-elected subject matter with that of Group I would not place a serious additional burden on the Examiner. "If the search and examination of the entire application can be made without serious burden, the examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions." M.P.E.P. § 803 (emphasis added). It is respectfully submitted that this policy should apply in this application in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Office.

With regard to the additional restriction to a particular sequence, Applicants note that the Office relies for support on Section 803.04 of the M.P.E.P., without providing citations. The passage is provided as follows.

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of **35 U.S.C. 121**. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an

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> independent and distinct invention, subject to a restriction requirement pursuant to **35 U.S.C. 121** and **37 CFR 1.141** *et seq*.

(M.P.E.P. § 803.04.)

However, the Office conveniently omits the passage that immediately follows, which *limits* the above-cited passage.

> Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of **37 CFR 1.141** *et seq*. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences,* 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined.

(M.P.E.P. § 803.04.) In this passage, the M.P.E.P. states that while the Patent Office would have had the right to restrict to individual sequences, it has waived that right, and has concluded that examination of ten sequences would not create an undue burden.

Thus, with regard to restrictions related to nucleotide, or amino acid sequences by extension, the Commissioner has *waived* the requirements on which the Office relies in the outstanding Office Action. If the Commissioner has reinstated these requirements, Applicants respectfully request that they be informed of such reinstatement. Or if the Office is now aware of binding rules or regulations that would change the 10-sequence allowance, then Applicants request to be informed of such information. However, in the absence of an *official* change in position, Applicants are entitled to have at least ten sequences examined.

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Finally, Applicants respectfully submit that the claims of Group I, which includes claim 1, all require the presence of the elements recited in claim 1. All of the claims of Group I are linked by these common recited features, and all of the sequences falling within the scope of claim 1 would require these features as well. For these reasons as well, Applicants respectfully submit that the Office should consider all of the recited sequences, or at the very least, ten in this application.

Conclusion

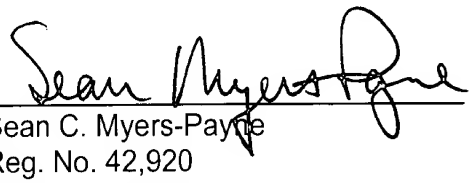
In conclusion, Applicants respectfully request that the Examiner withdraw the restriction requirements and consider all of the pending claims together.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 17, 2003

By: 

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APPENDIX TO AMENDMENT

IN THE SPECIFICATION:

The following change is made to paragraph [033]:

d) a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters which are contained in the same fragment, said nucleotide sequence [lacking] having its initiation codon. Optionally, the recombinant vector also contains a replicon which is functional in *E. coli*.

IN THE CLAIMS:

Claim 1 is amended as follows:

1. (ONCE AMENDED) Recombinant screening, cloning and/or expression vector[, characterized in] that [it] replicates in mycobacteria and [in] that [it] contains:

1) a replicon, which is functional in mycobacteria;

2) a selectable marker;

3) a reporter cassette comprising:

a) a multiple cloning site (polylinker),

b) optionally a transcription terminator, which is active in mycobacteria, upstream of the polylinker,

c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, and

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d) a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, said nucleotide sequence [lacking] having its initiation codon.

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